Duke | Robert J. Margolis, MD Center for Health Policy

Building a Common Risk Evaluation and Mitigation Strategies (REMS) Platform

Hotel Monaco • Washington, DC
June 7, 2016

1:00 p.m. **Registration**

1:20 p.m. **Welcome and Introduction**
Mark McClellan, Duke-Margolis Center for Health Policy

1:30 p.m. **Introduction to the Use Case Scenario: Prescriber Certification Data Standards**
Presentation: **Adam Kroetsch,** U.S. Food and Drug Administration

1:50 p.m. **Session IIIa Breakout: Identifying the Relevant REMS Data Elements for Prescriber Certification**
Objective: Participants will break out into small working groups to discuss the process and identify the data elements needed to carry out the REMS scenarios described. Workgroup discussion will be facilitated and focus on a specific information exchange scenario within the use case. Each workgroup will have a lead discussant to present their findings. Moderated discussion will follow presentations allowing for feedback on findings.

Moderator: **Steven Berman**, U.S. Food and Drug Administration

Questions to Address:

- What data elements need to be exchanged to successfully carry out each scenario? And between whom?
- What is the purpose of each data element?
- Where would the data come from?

2:45 p.m. **Break**

3:00 p.m. **Session IIIb Breakout: Refining the Process for Data Exchange under the REMS Provider Certification Use Case Scenarios**
Objective: Participants will break back out into working groups to develop and refine the process for exchanging data elements under the scenario discussed in the previous session. The objective is to identify opportunities to improve and refine the workflow process under these scenarios.

Questions to Address:

- How can we ensure that these processes:
    - Allow for the exchange of the necessary data elements,
    - Assure timely patient access to REMS drugs,
    - Are compatible with a wide range of healthcare settings, and
    - Support transfer of information across different settings of care?
- How might REMS Structured Product Labeling (SPL) support these processes?

- What considerations should be kept in mind when developing standards based on these processes?

3:30 p.m. **Presentation of Workgroup Findings and Group Discussion**
Objective: Following on the previous breakout session, each workgroup will have a lead discussant to present their refined process to the full group. Moderated discussion will follow presentations allowing for feedback on refined scenarios along with consideration of other relevant topics that could impact these scenarios.

Moderator: **Steven Berman**, U.S. Food and Drug Administration

4:35 p.m. **Closing Remarks**
Mark McClellan, Duke-Margolis Center for Health Policy

4:45 p.m. **Adjournment**